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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,890	01/29/2002	Timothy A. Coleman	PF537	3639

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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,890	COLEMAN ET AL.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-10,17,18,22 and 24-31* is/are pending in the application.

4a) Of the above claim(s) *10,18 and 28-31* is/are withdrawn from consideration.

5)☒ Claim(s) *26,27 and 30* is/are allowed.

6)☒ Claim(s) *1,2,6-8,17 and 22* is/are rejected.

7)☒ Claim(s) *9 and 25* is/are objected to.

8)☒ Claim(s) *1,2,6-10,17,18,22 and 24-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 19 February 2004 has been received and entered in full.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Newly submitted claims **28, 29,** and **31** are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 28 & 29 are drawn to nucleic acids and claim 31 is drawn a method of screening molecules that bind a scaffolded fusion polypeptide. The nucleic acids of claims 28 and 29 are independent and distinct from the instantly claimed polypeptide because none are required to make or use said polypeptide. The instant polypeptide can be made by materially different methods from said nucleic acids such as chemical synthesis. Claim 31 is drawn to a method of use for the instantly claimed product, the polypeptides. The instantly claimed polypeptides can be used in materially different methods such as to make antibodies, therefore they are independent and distinct from the method of claim 31.

4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims **28, 29,** and **31** are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn Objections And/Or Rejections

5. The Objection to the Drawings as set forth at pp. 3 6 in the previous Office Action (21 November 2003) is hereby *withdrawn* in view of Applicant's amendments (19 February 2004).

Maintained Objections And/Or Rejections

6. Claims **9** and **25** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims **1, 2, 6, 7, 8, 17, 22,** and **24** are rejected under 35 U.S.C. §112 ¶1 because the specification, while being enabling for *a soluble scaffolded fusion polypeptide comprising SEQ ID NO: 10 and/or SEQ ID NO: 31*, does not reasonably provide enablement for *any other soluble scaffolded fusion polypeptide.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make** or **use** the invention commensurate in scope with these claims for the reasons set forth at pp. 4-8 ¶8-19 of the previous Office Action (21 November 2003).

8. Applicant traverses this rejection on the following grounds: **(a)** the claims have been amended to recite the use of only on particular zinc finger motif (SEQ ID NO: 6 and 7), **(b)** the claims have been amended to recite that the scaffolded fusion polypeptide is soluble, **(c)** the only biological activity required by the claims is that the scaffolded fusion polypeptide binds an antibody that recognizes the native, properly folded form of the integral membrane protein from

which a functional domain was obtained, and **(d)** because the claims only require antibody binding by way of function, Ling *et al.* (1999) is irrelevant. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

9. On "**(a)**", Applicant's amendment has failed to address the underlying problem with full enablement of the claims. This is the issue of the total breath of the claims, not only the zinc fingers but the ill-defined "functional domain" and "scaffold domain" of which no clear guidance nor examples are presented as to fulfill the full breadth of the claims. While addressing which particular zinc finger may be used, this is only part of the claimed soluble scaffolded fusion polypeptide where the skilled artisan is still lacking adequate disclosure as to make and use said soluble scaffolded fusion polypeptide.

10. On "**(b)**", Applicant's amendment has failed to address the underlying problem with full enablement of the claims. This is the issue of the totality of the claims which encompass all polypeptides which contain ill-defined "functional domain" and are soluble. The Specification does not contain guidance nor examples are presented as to fulfill the full breadth of the claims. While addressing that the desired end product, the scaffolded fusion polypeptide, is soluble this is only provides clarification on part of the claimed soluble scaffolded fusion polypeptide where the skilled artisan is still lacking adequate disclosure as to make and use said soluble scaffolded fusion polypeptide.

11. On "**(c)**", Applicant's amendment has failed to address the underlying problem with full enablement of the claims. This is the issue of the totality of the claims which encompass all polypeptides which contain ill-defined "functional domain" and are soluble. The addition of language requiring a yet as disclosed antibody with a desired activity fails to provide clear

conception of what is being claimed, how to make it, and how to use it. Applicant has added a desired property to the desired end product but the skilled artisan is still lacking adequate disclosure as to make and use said soluble scaffolded fusion polypeptide with such the claimed property.

12. On "**(d)**", Ling *et al.* (1999) was used the Examiner to exemplify the breath and complexity of the claimed invention. Ling *et al.* (1999) discusses the minimal functional requirements of a chemokine receptor, a member of the claimed genus of "naturally occurring receptors". In addition, the Applicant's amendment adding the antibody specificity is insufficient to provide guidance as to what constitutes a "functional domain".

13. Claims **1, 2, 6, 7, 8, 17, 22,** and **24** are rejected under 35 U.S.C. §112 ¶1 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth at pp. 8-10 ¶20-25 of the previous Office Action (21 November 2003).

14. Applicant traverses this rejection on the following grounds: **(a)** the claims have been amended do define particular structures and specific activities, **(b)** Applicant is not required to "explicitly describe each of the trees in the forest" pursuant to *Union Oil Co. v. Atlantic Richfield Co.* , 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000), and **(c)** the Applicants have invented what is claimed. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

15. On "**(a)**", neither particular structures nor specific biological function have been provided for the "functional domain". The independent claim requires a "functional domain" but does not require that the functional domain to possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity. Thus, the claims are drawn to a genus of agents that is defined by having an undefined function.

16. To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

17. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004]. In *University of Rochester v. G.D. Searle & Co.* a patent directed to method for inhibiting prostaglandin synthesis in human host using an unspecified compound, in order to relieve pain without side effect of stomach irritation, did not satisfy written description requirement of 35

U.S.C. §112, since the patent described the compound's desired function of reducing activity of the enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since invention consists of performing "assays" to screen compounds in order to discover those with desired effect. The patent did not name even one compound that assays would identify as suitable for practice of invention, or provide information such that one skilled in art could identify suitable compound. And since specification did not indicate that compounds are available in public depository, the claimed treatment method cannot be practiced without compound. Thus the inventors cannot be said to have "possessed" claimed invention without knowing of a compound or method certain to produce compound. Thus said patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic a class of compound defined only by their desired properties.

18. On "**(b)**", the Examiner notes that Applicant has adequately described SEQ ID NO: 10 and SEQ ID NO: 31. But the remaining encompassed proteins have not been adequately described in any manner as to decipher their nature, structure, function, or identity (see above). Therefore based on the Specification the skilled artisan could only derive SEQ ID NO: 10 and SEQ ID NO: 31 from what has been taught therein. All other embodiments are desired end products of a suggested procedure of trial and error.

19. On "**(c)**", the genus of soluble scaffolded fusion polypeptides comprising soluble loops or strand of an integral membrane protein fused to scaffold domains comprising SEQ ID NO: 6 and 7 is so broad as to render it undefined and not described. The enormous range of possible combinations of proteins which meet the desired parameters is simply astronomical. The Specification contains only two examples of the completed desired protein with no apparent

guidance as to obtain more of such proteins. While soluble scaffolded fusion polypeptides may constitute a fecund ground for investigation, the CAFC ruled in *Genentech Inc. v. Novo Nordisk A/S* (CA FC) **42 USPQ2d 1001** (1997) that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Citing *Brenner v. Manson,* **383 U.S. 519, 536, 148 USPQ 689, 696** (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Therefore the CFAC stated that tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in the instant specification with respect to the any soluble scaffolded fusion polypeptides other than SEQ ID NO: 10 and 31.

Summary

20. Claims **26, 27,** and **30** are free of the art.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Elizabeth C. Kemmerer

CJN
May 3, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER